



Hans J. Michael GmbH



Celebrating its 10th Annual, the biggest HSE event in mainland Europe returns on 17 – 18 May 2016 with the ambition to grow not only in size but also in impact. Moving to the heart of European business, Frankfurt, the forum will focus on the idea of Visible HSE leadership by all.

New era of HSE Excellence starting in Frankfurt, May 2016

**17th - 18th May 2016: 10th HSE Excellence Europe
„Beyond the plateau: Visible HSE Leadership by All“,
The Westin Grand Frankfurt, Frankfurt am Main (D)**

The goal is to find out how to motivate your employees to step their game up and become ambassadors for health, wellbeing, safety and environment in your organisation. Because no matter how small the change is, with the right leverage it can go viral.

Bringing on board its most senior speaker panel to date, VPs and other top-level HSE executives (LOreal, Danone, Total, Etihad Airways, APM Terminals, Engie, Mondi Group, Credit Suisse) and representatives from leading associations (RoSpa, Campbell Institute and British Safety Council), will discuss major issues that will tackle the industry in the upcoming years. What are the future priorities for the Health and Safety system in Europe? What should 21st century leadership look like? How can you transform your employees into safety leaders? How will the influx of migrant workers impact Health & Safety in Europe?

A special keynote address will be delivered by Australian Motivational Speaker on Leadership, Teamwork & Safety Patrick Hollingworth, who will tell his story about a career spent at high altitude and how if

we work together as a team, we can all make it back down the mountain.

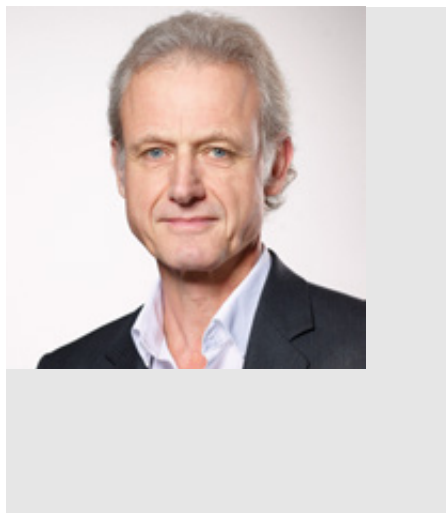
Several interactive features such as 2 focused workshops, roundtable discussions, 2-minute wisdom, an expanded exhibition area and book raffles are expected to create a highly collaborative environment and give the attendees the chance to find out about the best practices and innovative solutions in the field.

Fleming.

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New era of HSE Excellence starting in Frankfurt, May 2016	1
Environmental report details how new packaging concept for DuPont™ Tyvek® Classic Xpert can help reduce greenhouse gas emissions	3
Einstein put to the test – two precision experiments in space with lasers from Berlin	5
Cleaning processes benefit from cleaning baskets with open design	6
SHS acquires puracon	7
Cherwell improve support for pharmaceutical microbiology in Republic of Ireland	7
Humans and Robots in the Service of Patients	8
Flexi-Cap Protect by Schreiner MediPharm for Oncological Products: Protection Against Glass Breakage and Contamination	9
A key event for Switzerland's pharmaceutical and chemical market	10
Integrated Development of Drug Delivery Devices	11
International Powerhouses Announce Launch of ProFood Tech	12
Laminar Flow Box, cleanroom cell and CleanBoy	13
Particle Counting now in compliance with USP 787	14
New widefield confocal microscope ZEISS Smartproof 5 for industrial applications	15

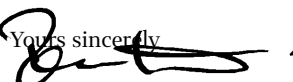
www.new-lounges.de



Dear readers, dear subscribers,

now it's February 2016 and we have a lot of interesting news and a lot of interesting events for your appointment calendar.

So the amount of the German and the international newsletters is constantly growing. We hope, we can give you with this information a good help for your daily work and your planning tasks.

Yours sincerely,

 Reinhold Schuster



The map shows where the readers of the cleanroom online newsletter are coming from: if you want to get in contact with these readers please contact us.



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Environmental report details how new packaging concept for DuPont™ Tyvek® Classic Xpert can help reduce greenhouse gas emissions

The results of a report (1), commissioned by DuPont, reveal that the new DuPont™ Tyvek® Classic Xpert Eco-Pack can have a significantly reduced impact on the environment when compared to its standard packaging format. Accordingly, over the entire lifecycle of the packaging (2), there is the potential to reduce the emission of greenhouse gases by three tonnes CO₂ equivalent, achieve a saving of 77,700 MJ of primary energy, and decrease solid waste by 820 kg. Besides the environmental benefits, the new Eco-Pack can help users of the garments avoid costs relating to the handling and disposal of packaging at the end of their useful life.

In its standard packaging form, each Tyvek® Classic Xpert garment is individually packed in a polybag together with a user manual (referred to as Instructions for Use, or IFU). 25 coveralls are then grouped within a value pack, and each box contains 4 value packs, making 100 garments per box. “As part of DuPont’s new Tyvek® Classic Xpert Eco-Pack packaging concept, the 25 garments within the value pack are no longer individually packed, and there is just one user manual per value pack. Hence the packaging saving equates to 100 percent in terms of the polybags, and 96 percent in IFUs,” explains Deborah Sondag, marketing specialist EMEA, DuPont Protection Technologies.

The report, entitled The Environmental Benefits of Packaging Reduction, and carried out by BIO by Deloitte, quantifies and compares the environmental impact of both packaging concepts using a standardized Life Cycle Assessment approach. As a first step, a life cycle inventory is created for the individual stages involved in the production of the polybags and IFUs, their delivery to DuPont (up-stream processes), their onward transportation to customers and ultimate disposal (down-stream processes). Thereafter follows an evaluation of their environmental impact in terms of global warming potential, air acidification potential, net water consumption, primary energy demand and waste generation.

Three separate scenarios were considered for the assessment, differing in terms of number of garments shipped, shipping distance and end-of-life scenario (landfill, incineration or recycling, depending on the waste management practice of the destination country). Based on a shipment quantity of 35,000 coveralls transported by truck to France (scenario B), the following benefits of Tyvek® Classic Xpert Eco-Pack over standard packaging were predicted:

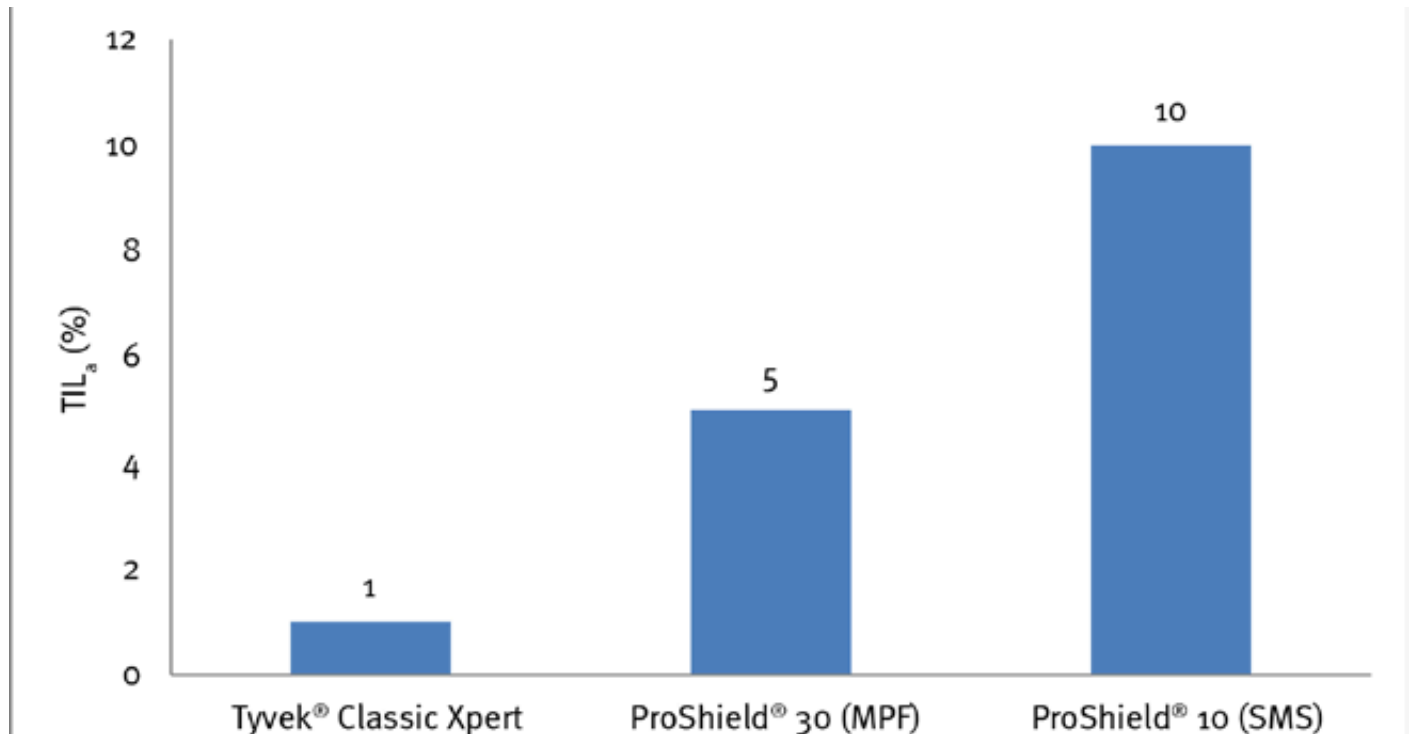
Impact category	Avoided amount	Unit				
Climate change	3045	kg CO ₂ eq	Equivalent to	The impact on climate change of	35	Paris-Toulouse flights for one passenger
Acidification	18	kg SO ₂ eq	Equivalent to	The impact on acidification of the monthly electricity consumption of	15	European inhabitants
Net Water Consumption	58	m ³	Equivalent to	The water consumption required for	332	Baths
Primary energy demand	77731	MJ	Equivalent to	The primary energy demand of the monthly electricity consumption of	14	European inhabitants
				The primary energy demand of	1698	Kg of crude oil
Waste creation	823	Kg	Equivalent to	The monthly municipal solid waste generation of	21	European inhabitants

Deborah Sondag continues: “In a context where environmental impacts are more and more important regarding the communication strategy of a firm, DuPont wants to provide its customers with clear environmental claims on these improvement actions, allowing them to easily integrate the related environmental benefits within their own environmental management program.”

Tyvek® Classic Xpert is the market-leading Type 5 (particulate) and Type 6 (liquid) disposable protective garment. Indeed, whilst there are many alternative garments also certified as providing similar levels of protection, a detailed look at their results delivers greater insight as to their actual barrier performance of the garment in question. For instance, the average total inward leakage of particles into a Tyvek® Classic Xpert garment, measured as part of the testing requirements for Type 5 protective clothing, is just 1 %. This compares favourably to 5% for a typical microporous (MPF) film garment or 10% for a typical SMS garment (see figure 2). Factors determining the particle barrier provided by the garment include the fabric used, seam construction and overall design.

Also in terms of providing a durable barrier to liquid, it is worthwhile looking at Tyvek® performance in closer detail: In tests used to determine the resistance of fabrics to liquid penetration and permeation, Tyvek® is demonstrated to provide a high barrier both before and after abrasion, while the levels of competitive materials are either inferior from the outset or fall away spectacularly after abrasion.

Environmental report details



Average inward leakage of various Type 5 protective suits (TIL_a, average value for 20 items in percentages for all activities in accordance with EN ISO 13982-2). Suits taped at mask, leg and arm seams and zip fastener covering. (Chart: DuPont)



The reduction in packaging associated with DuPont™ Tyvek® Classic Xpert Eco-Pack is clear to see (left: the packaging waste from a single standard box of 100 garments, right: the waste from a single Eco-Pack box of 100 garments). (Photo: DuPont)

(1) Bio IS were requested by DuPont de Nemours to produce a Report presenting the conclusions on the "Environmental benefits of packaging reduction". The Report was prepared for the DuPont de Nemours's confidential use, on the basis of contractual terms of reference agreed upon with the DuPont de Nemours to meet specific requirements and which may not be appropriate to meet the objectives of any other party who is a third party in relation to the Engagement entrusted to Bio IS. Its work should not be taken to supplant any additional inquiries or procedures that should be undertaken by a third party recipient of this attestation and it makes no representations regarding the sufficiency of the procedures it performed for the purpose of third parties. Bio IS release any responsibility of the use which could be made by the report by a third party. It didn't audit or otherwise test or verify the information given to it in the course of the services provided.

To conduct this report, Deloitte used the Lifecycle Assessment Method. Life Cycle-based approaches are now mandatory for all existing product standards (PAS 2050, GHG Protocol scope 3, European Product Environmental Footprint (PEF)) LCA carried out according to 14040 and 14044 ISO standards is:

- multi-steps, assessing potential impacts of a product all along its whole life cycle
- multi-criteria, taking into account a wide range of environmental issues (climate change, air acidification, water eutrophication, consumption of non-renewable natural resources, etc.)

(2) Based on a shipped quantity of 35,000 coveralls by truck to France.

Projects KALEXUS and FOKUS successfully carried out on board the sounding rocket TEXUS-53 in microgravity.

Einstein put to the test – two precision experiments in space with lasers from Berlin

According to Albert Einstein's theory of relativity, all bodies in a vacuum regardless of their properties are accelerated by the Earth's gravity at the same rate. This principle of equivalence applies to stones, feathers and atoms alike. Under the conditions of microgravity very long and precise measurements can be carried out to determine whether different atoms of different mass actually „fall equally fast“.

For the first precision measurements in space with cold atoms, potassium and rubidium are suitable candidates. In preparation for the measurements two experiments were conducted at the same time onboard a sounding rocket launched from Kiruna, Sweden, on January 23. Preliminary analysis of the data shows that the campaign was successful. The Humboldt Universität zu Berlin (HU) and the Ferdinand-Braun-Institut, Leibniz-Institut fuer Hoechstfrequenztechnik (FBH) test modern laser technologies within the framework of the projects KALEXUS and FOKUS. The demanding technology demonstrators lay the foundations for the precision tests of the equivalence principle with so-called potassium and rubidium atom interferometers as well as for further experiments aiming at tests of Einstein's theory of relativity. Researchers are hoping that eventually these experiments will provide the information needed to address one of the greatest challenges of modern physics: The unification of gravity with three other fundamental interactions into one comprehensive theory.

Laser experiments with potassium and rubidium atoms: KALEXUS and FOKUS

A stable laser system for the manipulation of potassium atoms was set up in the project KALEXUS under the guidance of the Optical Metrology group at HU. The centerpiece consists of two micro integrated semiconductor laser modules developed by FBH. In KALEXUS the wavelength of these laser modules is matched to an atomic transition of potassium. During the six-minute period of microgravity the experiment automatically stabilizes the wave-length of both lasers. In addition, the laser system can autonomously switch back and forth between the laser sources during flight. After all, such experiments are not easy to repeat, and scientists cannot take corrective action during the flight. Moreover, the measurements may not be compromised if one of the lasers should fail.

Another laser module designed by FBH and assembled by HU took part in the FOKUS campaign, which is managed by Menlo Systems. A laser was stabilized to an atomic transition of rubidium in order to demonstrate the technological maturity of corresponding technology for subsequent drop tests of atoms under microgravity conditions. The laser system also allows for clock comparisons. Here, the frequency of an „optical oscillator“, the laser, is compared to the



frequency of a quartz oscillator that „ticks“ in the radio frequency range, like a modern wristwatch. The general theory of relativity presumes that the „ticking“ of all clocks is affected by gravity in the same way, regardless of how these clocks are implemented physically and technically. An initial test in April 2015 confirmed the suitability of such „atomic clocks“ and of the laser systems required to test the general theory of relativity in space. The goal is now to confirm the initial results after some technical improvements have been applied to the system.

Two applications of technology in direct comparison

The two experiments use different types of lasers from the FBH. This allows a comparison of the different laser technologies for the application scenario. The centerpiece of the FOKUS module is a DFB (Distributed Feedback) laser, which emits light in a narrow frequency or wavelength range at 780 nm. This spectrally narrow bandwidth is one of the key requirements for the laser module, which is used for the spectroscopy of rubidium atoms and thus for precision measurements.

KALEXUS uses an ECDL concept (Extended Cavity Diode Laser), which thanks to an external grating, provides an even narrower linewidth. The laser is optimized for spectroscopic measurements with potassium atoms and emits at a wavelength of 767 nm. However, the external grating makes it potentially more prone to malfunction - as opposed to the monolithic structure of the FOKUS laser. Ultimately, the palm-sized modules have to withstand the mechanical loads during rocket launch with accelerations of up to 15 times the acceleration of gravity and have to function trouble-free in space.

The projects KALEXUS and FOCUS are financed by the German Center for Aerospace (DLR).

About the Joint Lab Laser Metrology

Narrow-linewidth diode lasers, i.a., for precision optical spectroscopy in space, are developed by the joint lab. The Ferdinand-Braun-Institut and the Research Group on Optical Metrology of the Mathematics and Natural Sciences Faculty of the Humboldt-Universität zu Berlin work closely together here. This allows the common interests and complementary expertise of HU and FBH to be bundled optimally.

Ferdinand-Braun-Institut
D12489 Berlin

Cut unit costs with workpiece holders and baskets designed for optimum cleaning

Cleaning processes benefit from cleaning baskets with open design

These days, defined cleanliness specifications are common in component production across virtually all sectors. To comply with these specifications, some companies are investing vast sums in systems engineering and process technology. However, one major factor is often not considered: the cleaning basket. This is very critical as the cleaning basket influences effectiveness of the costly process technology significantly, and thus the costs of cleaning.



In contrast to boxes from perforated sheets the baskets from stainless steel rounds have no enclosed surfaces, corners and edges. Cleaning media and process technology have unfettered access to the parts to be cleaned.

In most cases, adapting or optimising a cleaning process revolves around systems engineering, process technology and the cleaning media. What tends to be forgotten is that process technology such as ultrasonics, spray jets and cleaning media may only work to best effect on parts to be cleaned when they can reach those parts properly – and it is the cleaning basket used that determines the level of effectiveness. Incorporating baskets and workpiece holders into the considerations at an early stage is therefore worthwhile.

Accessibility from every angle

The optimum cleaning effect is achieved where the workpieces in the basket are easily accessible from all sides for the process technology and the media. To facilitate this, Metallform produces workpiece holders and baskets for bulk parts from stainless steel rounds. In contrast to boxes from perforated sheets that are still often used, these baskets have no enclosed surfaces, corners and edges. Therefore, ultrasonics and spray jets have unfettered access to parts and can take maximum effect. At the same time, the open design ensures an effective exchange of media. On the one hand, removed contaminant is flushed from the basket quickly and can be removed by the filter and the accumulation of contamination in the basket is inhibited. On the other hand, the carry-over of cleaning media is minimised, resulting in longer periods between bath changes and thus improved system availability. In addition an open basket design allows cost savings in the drying process, as the easy accessibility of parts reduces the drying time required.

Optimum adjustment of workpiece holders to parts

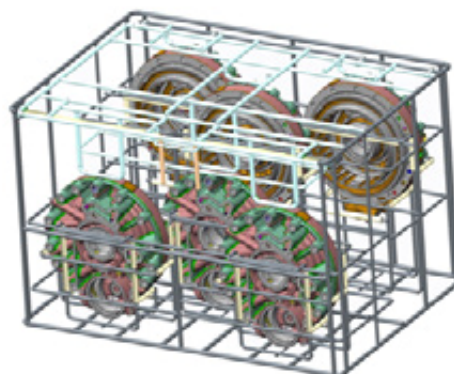
Early integration of cleaning baskets also enables these to be adapted effectively to the cleaning machine and the workpieces to be cleaned. One consideration in this context is the optimum positioning of components in the workpiece holder. To achieve this, Metallform uses CAD technology. The optimum positioning of components enables the process technology being used to access critical areas such as specific bore holes and undercuts. In this way, particles and film-like contamination are quickly and reliably removed and the effective, resource-efficient drying of parts is assured. Another design feature is the minimising of contact points between the component and the workpiece holder. This also helps to ensure cleaning of consistent quality within a short time.

Stainless steel for long lifetime and maximum security

Metallform produces all workpiece holders and baskets from stainless steel rounds with electrolytic polished surfaces. With good reason: This high quality, durable material is suitable for all cleaning media and prevents components from being recontaminated by the workpiece holder and baths from being contaminated by corrosion and zinc separation. Aside from the design and material, the workmanship of the cleaning baskets is equally convincing. All joints are completely welded and there are no sharp corners, edges or wire ends that could cause injury.

A basket designed for optimum cleaning may not improve the cleaning machine, but it ensures that process technology (which is generally expensive) can work to maximum effect.

Metallform Wächter GmbH
D 75004 Bretten



By the optimum positioning of components in the workpiece holder critical areas such as specific bore holes and undercuts can be treated specifically.

One of the funds consulted by the Tübingen based company, SHS Gesellschaft für Beteiligungsmanagement mbH, has acquired puracon's business operations from the insolvent predecessor company.

SHS acquires puracon

Based in Rosenheim, puracon is a packaging specialist focused on the sterile assembly and packaging of medical devices and implants in GMP certified cleanrooms. The range of services that it provides its globally active customers also includes consultancy with regard to all regulatory issues as well as conducting the required testing, certification and validation in compliance with the respective national directives. Puracon realigned its business in light of increasingly stringent regulatory requirements in 2013/2014.

„With its business model, Puracon is active in a fast-growing market driven by the increasing number of regulatory restrictions being imposed by legislators. We will assist puracon in its expansion – especially internationally – so that the company can establish itself even more solidly in the future as a market leader in a dynamic environment“, says Uwe Steinbacher, Managing Partner at SHS.

„We are glad to have found a new owner for puracon in the experienced medical technology investor SHS, which will accompany

the company's continued growth, stand for stability and continuity and thus offer exceptional perspectives for our customers as well“, explains Sascha Kocis, Member of the Board at puracon.

With its acquisition of puracon, SHS is further pursuing its stated investment strategy. With a fund volume of 125 million euro, SHS is currently focusing its investment on expansion financing, changes in shareholder structures and successor situations. The Tübingen based investor is planning further acquisitions and investments in the fast-growing medical technology and life-science industries in the months ahead.

SHS Gesellschaft für Beteiligungsmanagement mbH
D 72072 Tübingen

Redipor® prepared media to be supplied directly to customers

Cherwell improve support for pharmaceutical microbiology in Republic of Ireland



Redipor® Prepared Media from Cherwell Laboratories

Cherwell Laboratories, specialists in cleanroom microbiology solutions for the pharmaceutical and related industries, will now be delivering their Redipor® prepared media directly to customers in the Republic of Ireland. Cherwell are renowned for offering a flexible supply of quality prepared microbiological media products, and this development will now enable Cherwell to offer improved service and support to customers in the Republic of Ireland.

Since some of the leading international names in the pharmaceutical industry operate manufacturing sites in Ireland, Cherwell recognises the importance of this market for environmental monitoring, product sterility testing, as well as operator and process validation.

Andy Whittard, Managing Director, Cherwell Laboratories commented, “Our recent investment in resources and expertise within the company now allows us to focus on regions where our Redipor product is not established. By developing closer relationship with customers it will allow us to ensure we deliver the best prepared media solutions and dedicated customer service.” Cherwell will now ship Redipor product directly from their UK manufacturing facility in Oxfordshire to customers in the Republic of Ireland.

To further enhance their customer service and support in that region, Cherwell are also currently recruiting for a Sales Specialist, based in the Republic of Ireland. Cherwell Laboratories' Sales Manager, Andrew Barrow remarked, “While we pride ourselves on the customer service we provide by phone and email, we appreciate the importance of having support locally that customers can contact. Fulfilling this new role will help us to build and maintain links with customers, allowing us to fully understand and satisfy their needs.” Cherwell will continue to work with their distributor in Belfast, Davidson & Hardy, for the supply of Redipor products in Northern Ireland.

Further demonstrating their commitment to the Irish market, Cherwell have also recently become a corporate member of the Irish Cleanroom Society. The society provides a forum for the exchange of ideas and working practices, a support network and works closely with the Cleanroom Testing and Certification Board to run a series of training courses.

Cherwell Laboratories Ltd
OX26 4XB BICESTER
Vereinigtes Königreich Großbritannien und Nordirland

AUTOMATICA 2016 – Professional Service Robotics

Humans and Robots in the Service of Patients



Service robotics is revolutionizing medicine and healthcare; High-tech is providing more quality from surgery to rehabilitation. In the creation of diagnoses, for complicated surgical procedures as well as in everyday hospital work, service robots are becoming the perfect teammates of people. AUTOMATICA takes a look at the protagonists of a new era in Munich from June 21 to 24, 2016.

21.06. - 24.06.2016: AUTOMATICA 2016, München (D)

Freedom from wheelchairs thanks to iron man

Robots have many faces. As exoskeletons, they relieve workers as a stable outer shell when they lift and carry heavy objects. ReWalk Robotics applied this idea to quadriplegic people to enable them to walk again. As a result, the company won the first ESA BIC Start-up Award at AUTOMATICA 2014. The customized exoskeleton improves function, safety and alignment of joints. The patient can go for a walk, enter buildings without a ramp, hold conversations at eye level and is more independent. This affects his bone density and his body fat positively, improves posture and reduces pain; he is part of society again. The exoskeleton is also used in hospitals for exercises and therapy.



ReWalk Robotic Exoskeleton won the first ESA BIC Start-up Award at AUTOMATICA 2014. (Photo: Messe München)



The Chairless Chair facilitates many activities in assembly. This high-tech construction made of carbon lets Audi employees sit without any chair. At the same time, it helps to improve posture and reduces leg strain. (Photo: Audi)

Robots—a knack for surgery

The precision of a service robot provides enormous benefits in surgery both for doctors and patients. CARLO (Computer Assisted, Robot-Guided Laser Osteotome) from Advanced Osteotomy Tools (AOT) AG is a pioneer in the operating room; it cuts bones contactless and carefully thanks to laser light. During this, sensors and the doctor control it continuously, which ensures safety and high-precision removal. “This means an optimal safety of the intervention and faster healing for the patient,” Dr. Alfredo Bruno, CEO of AOT AG, explained.



Robot CARLO (Computer Assisted Robot-guided Laser Osteotome) cuts bones contactless and highly accurately. (Photo: AOT AG Basel)

Hope for cancer patients

Service robotics also enables gentle treatment in radiosurgery. For example, cyberknife technology developed at Stanford University treats tumors highly precisely to sub-millimeters using mobile robotics and digital imaging. “The treatment is given to people as outpatients and is painless; the surrounding tissue receives significantly less radiation, and an operation is unnecessary. The patient can usually resume his normal agenda immediately after treatment,” explained Professor Dr. Alexander Muacevic from the European CyberKnife Center, which has already performed 6,000 such treatments successfully.

Treating a patient in radiotherapy correctly and accurately is becoming increasingly trickier, because the number of recognized and treated structures is increasingly and they are increasingly fine. With the positioning system from Buck Engineering & Consulting (BEC)



A cancer patient in the treatment room just before radiosurgery treatment using the most advanced CyberKnife System M6. The CyberKnife headmounted attachment shows the latest lens attachment “InCise 2 Multileaf Collimator”, which was used for patient care for the first time worldwide in Munich. (Photo: European Cyberknife Center Munich-Grosshadern)



In May 2015, the first ceiling-mounted BEC positioning system for patients was used at MedAustron, the Austrian center for ion therapy. (Photo: Thomas Kästenbauer)

Humans and Robots in the Service of Patients



Together with Oppent SpA Milano, BlueBotics SA in Lausanne designed a complete software program for an automatic vehicle in hospitals. The centerpiece is a solution for mobile service robots to control the flow of traffic. (Photo: Oppent)

GmbH, patients can be positioned flexibly, aligned precisely and irradiated accurately. "The economic efficiency of the radiation source increases, which is a positive aspect for operators of radiotherapy centers and manufacturers of such equipment," Managing Director Matthias Buck explained.

More care and attention in hospitals

Driverless transport systems are experiencing a boom. They take care of routine tasks for nurses around the clock. For those receiving care, this means more personal attention, optimal care and increased satisfaction. One example is the autonomous mobile delivery robot TUG® from Aethon. In hectic hospital environments, it transports goods between pharmacy, laboratories, environmental services, food distribution, laundry service and blood bank. BlueBotics SA developed the automatically controlled vehicle EVOcart™ for hospitals jointly with Oppent SpA. Navigation is via laser scanning and requires no signs on the floor, walls or ceiling. EVOcart™ won 2nd place in the Service Robotics Masters Award at AUTOMATICA 2014.

AUTOMATICA: The trade fair for automation

AUTOMATICA is the leading trade fair for industrial automation and mechatronics. It is a four-day show that will give you a comprehensive look at the latest developments in automation.

Messe München GmbH
D 81823 München

Schreiner MediPharm at Pharmapack Europe in Paris

Flexi-Cap Protect by Schreiner MediPharm for Oncological Products: Protection Against Glass Breakage and Contamination



Schreiner MediPharm has further developed Flexi-Cap, its innovative first-opening indication security concept, for oncological applications: An additional cap protects the bottom of bottles or vials against glass breakage and surface contamination. Schreiner MediPharm will present the novelty as a product highlight at Pharmapack Europe in Paris from February 10 to 11, 2016.

**10th - 11th February 2016:
Pharmapack 2016, Paris (FR)**

Flexi-Cap Protect works as follows: In addition to the cap which covers the closure and upper part of the container, a second cap is added to protect the bottom and lower part. Both caps are affixed to the container using a label, which can optionally be provided with an integrated foam layer to provide further protection against lateral impact. Consequently, the container's surface is completely protected. Another important aspect: The two caps and label are applied without heat, so that the medicine's properties are not impaired. In addition, the upper cap offers space for imprinting warning notices, codes for track & trace systems or integrating NFC inlays for interactive applications.

Cytostatics are highly potent substances to combat cancer cells, but they are extremely toxic for healthy cells. Therefore, it is imperative to protect packaging against surface contamination and glass breakage. In spite of sophisticated filling and packaging processes in the production of pharmaceuticals, contamination of primary packaging cannot be completely avoided. Moreover, glass breakage of primary containers with cytostatics can have serious consequences.

„The different functions of the newly developed special solution Flexi-Cap Protect ensure the protection of users against the severe consequences of possible contamination and simultaneously guarantee the integrity of primary packaging,“ highlights Ann L. Merchant, President of Schreiner MediPharm.

Schreiner MediPharm
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ILMAC 2016

A key event for Switzerland's pharmaceutical and chemical market



ILMAC has been Switzerland's sole trade fair for process and laboratory technology since 1959. Every three years, more than 12,000 specialists from the pharmaceutical, chemical, biotechnology, cosmetics, food and drinks industries meet up at Messe Basel. In addition to fostering their business relations they come to find out about the latest approaches and solutions in the field of industrial applications for process and laboratory technology. Under the motto ILMAC 4.0, current industry topics such as boosting efficiency, reducing costs and the latest trends will be discussed in the ILMAC Forum. The next ILMAC is being held from 20 to 23 September 2016 in Basel as part of the Basel Life Science Week.

20.09. - 23.09.2016: ILMAC 2016, Basel (CH)

Switzerland is world champion in innovation

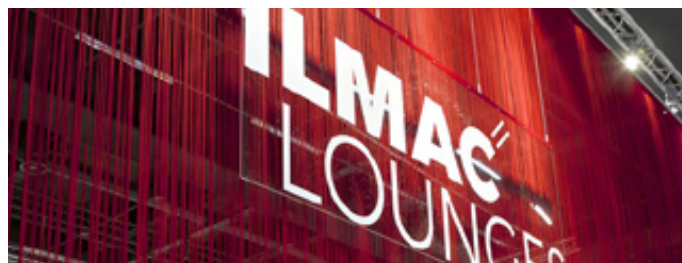
World sales of the top ten Swiss chemical and pharmaceutical companies totalled 144 thousand million Swiss francs in 2014. And, in this same year, the pharmaceutical companies alone spent more than six thousand million Swiss francs on research and development in Switzerland. This accounts for around 33% of their global R&D expenditure. The companies' high financial investment in Switzerland as a research location testifies both to the importance of the location and the innovative spirit that drives them. The European and global innovation index shows that Switzerland is not only European champion when it comes to innovation but world champion too. In addition to their R&D expenditure, Switzerland's pharmaceutical companies have also invested more than four thousand million Swiss francs in plant and systems, such as technical appliances, machinery, fittings for buildings and manufacturing equipment. As Roche recently announced, it will be investing 300 million Swiss francs in a production plant in Kaiseraugst, Switzerland, for the production of a new generation of specialist drugs.

Basel as a key life science region in Europe

Almost two thirds of those employed in the Swiss pharmaceutical industry work in the life science cluster in the Basel region. The major part of the added value generated in Switzerland thus originates in Basel and its surroundings. Approximately a third of all Swiss exports and a fifth of all Swiss imports are attributable to pharmaceutical products.

ILMAC trade fair in close proximity to the market

Since it was founded in 1959, ILMAC has developed into Switzerland's leading supplier fair for the pharmaceutical, chemical, food, drinks, cosmetics and biotechnology industries and covers all the industrial applications for process and laboratory technology. These sectors are moving ever closer together on the market, since the processes are increasingly no longer being planned and implemented individually within the companies but on a holistic basis instead. This development will be reflected at the 20th ILMAC with its state-of-the-art positioning concept. Michael Bonenberger, Exhibition Director for ILMAC, explains: „The exhibitors will be positioned in a mixed layout, thus permitting specially tailored synergies between the different sectors. In this way, the professional visitors can experience all the different areas of the trade fair as a single entity.“



Despite this wide variety, ILMAC will still be clearly laid out and will cover the full range of products and services in close proximity to the market. The concept is meeting with approval in the industry. Compared with ILMAC 2013, by the end of November, 50% of the exhibitors had already decided to take part again.

Concentrated life science power in 2016

The international Life Science Congress and also MipTec, the International Life Science Exhibition, are being held in the Congress Center Basel while ILMAC is running. MCH Swiss Exhibition (Basel) Ltd. has cooperated with Congrex Switzerland in the past already. They will now be working together even more closely, exploiting synergies and spanning the full range of activities from the scientific events right through to the practically-oriented ILMAC. In the week from 19 to 23 September 2016, all the events are being staged in the joint framework of the „Basel Life Science Week“.

Strong partner

With Endress+Hauser as the Main Partner Process, one of the world's leading suppliers of measuring devices, services and solutions for industrial process engineering and automation, is supporting ILMAC. Endress+Hauser has subsidiaries on all six continents and employs more than 12,000 employees in production, marketing and service worldwide.

1Source: Pharma-Markt Schweiz, Issue 2015, Published by Interpharma, Verband der forschenden pharmazeutischen Firmen der Schweiz.

ILMAC

MCH Messe Schweiz (Basel) AG
CH 4005 Basel

Phillips-Medisize – Pharmapack, Paris

Integrated Development of Drug Delivery Devices

**10th - 11th February 2016: Pharmapack, Paris (FR)**

Phillips-Medisize will show specialized visitors its expertise in designing, developing and manufacturing drug delivery devices as well as pharmaceutical primary packaging made of plastics during the Pharmapack exposition in Paris on 10-11 February 2016. A wide variety of products will be displayed, ranging from special drug delivery devices, dosage systems, disposable insulin pens, inhalers, mixing injectors, bottles and caps, on to sterile multi-chamber bags. Phillips-Medisize offers customers complete end-to-end service, from the idea to the finished solution, inclusive of drug handling and supply chain support. Its strong points on the market are especially drug delivery and dosage systems, which undergo cross-process inspection through high-priority quality assurance in accordance with ISO 13485 and FDA standards as well as GMP (Good Manufacturing Practice).

During the Pharmapack Europe Conference 2016 – on 10th February 2016, at 4 pm – Bill Welch, Chief Technology Officer, Phillips-Medisize Corporation, will give a lecture entitled „Integrated Development and Scale-Up of Combination Products“.

Key Points:

- Smaller and smarter combination products to support the trend toward patient-administered drug delivery
- Integrating HFE and DFM/DFA as foundations of the combination product development process
- Early manufacturing involvement to speed up time-to-market and reduce risk by “getting it right the first time”
- Development of a manufacturing scale-up strategy, concurrent with the development process

Abstract:

The combination of drug, with an appropriately designed delivery device, can have a profound effect on the intended user. However, there are many challenges to creating a successful combo-product including regulatory, clinical, human factors and drug/device interactions. Add to these challenges the need to manage complicated supply chain logistics, from design, testing and development through low volume clinical trial manufacturing and scale up into higher-volume production for commercialization. Project success and the ability to control the many variables in combination product development, depends upon the ability to select the right device development and manufacturing partner, with the right mix of development support and commercial manufacturing service offerings to help guide the project. This presentation discusses a well-rounded approach for biopharma companies interested in developing and commercializing successful combination products, by highlighting key device development and scale-up activities as well as their relationship to the overall combination product development process.

Speaker Info:

Bill Welch, Chief Technology Officer,
Phillips-Medisize Corporation

Bill Welch has over 25 years of contract design, development, and manufacturing experience, primarily serving customers in the drug delivery, medtech, and diagnostics markets. In his current capacity as Chief Technology Officer at Phillips-Medisize, he leads a global, 450+ person development, engineering, tooling, program management, and validation organization with more than 75 concurrent programs. He also has responsibility for the company's China operations, including recently developed capabilities such as the manufacture of Class 2 drug delivery devices and CFDA registration services for its customers. Bill has been with Phillips-Medisize since 2002, and was previously employed in the injection molding and electronic circuit fabrication/assembly contract manufacturing segments. Bill holds a BS from the University Minnesota - Duluth.

**Press Conference:**

Phillips-Medisize will give a one-hour press briefing during the Pharmapack show, which will include an industry update by Matt Jennings, Chairman and CEO. Key topics will cover:

- Continued growth and expansion of our design, manufacturing, and supply chain capabilities in a changing regulatory landscape to support customers on combination products.
- The impact of continued growth of large molecule injectable therapies for the development of wearable drug delivery devices, such as on-body infusers.
- Update on how leading medical device and pharma companies are leveraging Phillips-Medisize's design, manufacturing and regulatory support footprint in China, for the Chinese market.

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PMMI, Koelnmesse and IDFA Join Forces to Offer a New North American Food and Beverage Processing Event at Chicago's McCormick Place in Spring 2017.

International Powerhouses Announce Launch of ProFood Tech



**04th - 06th April 2017: ProFood Tech 2017, Chicago
(Illinois) (USA)**

Three trade show leaders joined forces to announce the launch of ProFood Tech, a new event that will focus on processing technologies serving the food and beverage industry. ProFood Tech will make its debut April 4-6, 2017, at McCormick Place, in Chicago, Ill.

The event is powered by three of the world's trade show leaders - PMMI, The Association for Packaging and Processing Technologies; Koelnmesse and the International Dairy Foods Association (IDFA). PMMI is the owner and producer of the PACK EXPO portfolio of trade shows and represents North American manufacturers of equipment, components and materials for processing and packaging. Koelnmesse organizes world leading trade shows for the food and beverage industries as well as for the food and beverage processing industries, such as Anuga and Anuga Food Tec in Cologne, Germany. IDFA is North America's largest dairy association, representing more than 85 percent of all North American manufacturing of dairy products.



„In assessing the current trade show landscape, we saw there was a need for a dedicated event that brings buyers together with leading world-wide manufacturers in the food and beverage industry,“ says Charles D. Yuska, president and CEO, PMMI. „ProFood Tech provides a venue to share the latest innovations and crossover technologies from multiple vertical markets within the food and beverage industry and will be that one-stop-shop featuring exhibits from both large companies that serve several customer segments and smaller niche companies with focus on more specific needs.“

Exponential changes in technology are making it hard for food and beverage companies to keep up. ProFood Tech will provide a wide perspective on the food and beverage processing industry as a whole and feature cutting edge solutions to the challenges the industry is facing every day on the plant floor.

More than a trade show, ProFood Tech provides both large and small suppliers the opportunity to build their businesses by breaking into new food and beverage markets, cementing their status as industry leaders and reaching a large group of customers at one event. „In a close dialogue with leading technology suppliers from around the globe, we aim to create a market platform in the United States that

is tailored to the requirements of domestic and foreign exhibitors and visitors,“ explains Gerald Böse, president and CEO of Koelnmesse. „Over a period of decades, Koelnmesse has established an excellent reputation world-wide as a trade show organizer, especially in the field of food products and food technology. Examples include the leading international trade fair Anuga, the world's biggest and most important trade show for the food industry, as well as related spin-offs around the world.“

„Pro Food Tech,“ Böse adds, „marks a further logical step in Koelnmesse's strategy aimed at offering expert support to our customers in various target markets in our role as a global service provider.

With an expansive show floor and enhanced educational programming led by IDFA, ProFood Tech will attract high-level buyers from every food and beverage sector. „The opportunities for new ideas and break-through solutions are amazing when executives from related businesses come together to discuss, review and experience the innovations, products and services available today,“ said Connie Tipton, president and CEO of IDFA. „IDFA is proud to partner with these trade show leaders and to continue our tradition of bringing industry suppliers, processors and manufacturers together so they can find profitable business solutions, discover new technologies and see the innovations that are abundant in our industry.

Industry leaders, including Delkor Systems, Inc. and Tetra Pak, are excited about the opportunities that ProFood Tech will offer

„As a longtime member of both IDFA and PMMI, Delkor is very pleased to see the attention and focus that ProFood Tech will bring to the North American food and beverage industry,“ says Dale Andersen, president and CEO of Delkor Systems, Inc. „Koelnmesse's outstanding reputation as a trade show organizer only strengthens this collaboration.“

„As a world leader in processing and packaging technologies, Tetra Pak is excited about the potential ProFood Tech holds,“ says Carla Fantoni, vice president of communications for Tetra Pak U.S. and Canada. „The joint efforts of PACK EXPO, Anuga and IDFA clearly demonstrate a commitment from these three leading organizations in establishing a trusted brand in serving all food and beverage categories. We think this consolidated approach will help suppliers and customers alike make the most of the show.“

ProFood Tech is a totally unique endeavor with the collaboration of three of the world's leading industry organizations, all with ownership of this initiative. The new show will combine the unrivaled experience and recognition of PACK EXPO, Anuga and IDFA to create an event that will be unprecedented in its ability to address all of the issues facing food and beverage processing operations in the North American marketplace like sustainability, improved operations and food safety.

Koelnmesse GmbH
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Reinraumzelle mit festen Wänden aus Aludibond oder Acrylglas



Laminar Flow Box FBS wahlweise mit Untergestell und Schrank

Laminar Flow Box, cleanroom cell and CleanBoy



In industrial manufacturing as well as in science and research the need for a particle-clean and germ-free environment plays an ever important role.

For this purpose elaborated clean room facilities are being designed at great expense not only upon purchase but also for their keep-up. In many instances it is absolutely excessive to install oversized, technically complex, and expensive clean room facilities. Often the economy of an exclusive clean room does not justify for it. In many instances it is quite sufficient to create a localized clean room environment.

The Spetec Flow Box FBS or "CleanBoy" has been developed exactly for this purpose.

The use of a Laminar Flow Box or a "CleanBoy" establishes clean room conditions at the location where they are needed.

For the manufacturing of the Flow Box FBS only high quality materials such as acrylic glass and stainless steel are being applied. For installation in an acidic atmosphere a special protective coating will be offered as an option. The effective clean room space of the FBS covers a size between 2,5 square feet and 12,9 square feet.

The Flow Box is equipped with a filter of the type H 14. This filter is capable of removing 99,995 % of all particles having a size larger than 0,5 µm (EU 14).

Even for particles larger than 0,21 µm the degree of filtering is still 99,95 % . In this case the retention factor is 10^3 which means that the air quality in the Flow Box versus the outside air will improve by a factor of 1.000. For particles larger than 0,5 µm an improvement by a factor of 90.000

will be obtained .

At an air flow velocity of 0,45 m / sec. the air stream occurs laminar, which means that the air moves as a parallel stream.

The „CleanBoy“, available as a standalone or tabletop device, offers a cost-effective and simple solution to the particle problem. The "CleanBoy" is simply set up and is ready to use immediately with no further installation.

The "CleanBoy" is available in the following versions:

- CleanBoy Mini - Tabletop version
- CleanBoy Maxi - Standalone version
- CleanBoy Flexi - Flexible with regards to size, shape, and equipment

The mobile clean room cell is a further option for an economical alternative to a complete clean room. It is made from anodized or acid-resistant plastic-coated aluminium or stainless steel profiles and can be set up in any laboratory, production room/hall, or office without having to take structural measures. A complete clean room workstation can be installed in the clean room cell.

The booth itself is surrounded by a PVC strip curtain or in order to create a sealed unit. Materials like dibond panels, acrylic glass or safety glass are also possible. The profile technology allows you to customize the size and shape of the clean room booth at will up to a freely selectable size.

The effective clean room area can be varied by combining individual laminar flow modules of various sizes. Even production lines, conveyors, or packaging machines can



CleanBoy Maxi - Standversion

be integrated into the clean room booth. Clean room category 100 is attained by using H14 filters. Due to the laminar air flow, there is no exchange of impure outside air underneath the flow modules.



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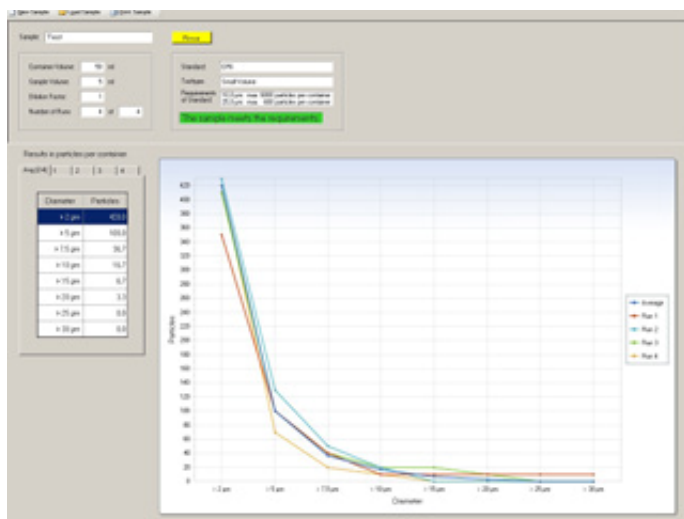
Pharmaceutical procedural software PAMAS USP

Particle Counting now in compliance with USP 787

The German company PAMAS develops, manufactures and distributes Automatic Particle Counters for fluid contamination control. For the analysis of pharmaceutical liquids, PAMAS offers a pharmaceutical procedural software programme, enabling the report of particle counting results in compliance with international pharmacopoeia. Before the introduction of the new feature, the programme PAMAS USP already fulfilled the standards USP 788 (Particulate Matter in Injections) and USP 789 (Particulate Matter in Ophthalmic Solutions). With a special accessory for small sample volumes, the particle counting systems PAMAS SVSS and PAMAS SBSS can now be upgraded, so as to meet the regulations of the USP 787 pharmacopoeia for Subvisible Particulate Matter in Therapeutic Protein Injections.



The particle analysing system PAMAS SBSS may be optionally equipped with a small pressure container. With the help of this feature, smallest sample volumes of higher viscosity, like Therapeutic Protein Injections, can be analysed as per USP 787. (Picture: PAMAS)



Particle counting systems can be equipped with software to report measuring results in compliance with international pharmacopoeia. The measuring result of the PAMAS USP pharmaceutical procedural software shows whether the sample meets the requirement as per USP 787 (Subvisible Particulate Matter in Therapeutic Protein Injections), per USP 788 (Particulate Matter in Injections) or per USP 789 (Particulate Matter in Ophthalmic Solutions). (Screenshot: PAMAS)

Excessive particulate contamination e.g. in infusion solutions or other liquid medicine may lead to health injuries. Particle analysing techniques can be used to measure particle contamination in these liquids or to make sure that pre-defined limits are not exceeded. In the pharmaceutical sector, analyses are usually done in compliance with official standards of the United States Pharmacopoeia (USP). According to the USP, pharmaceutical fluids, including infusion solutions, parenterals, pharmaceutical suspensions and intravenous or ophthalmic solutions, can be analysed with an automatic particle counter. This measuring device counts contaminants in liquids and classifies them into particle size classes.

Among many other particle counter models, the PAMAS product range offers two devices that are specially designed for pharmaceutical applications: the PAMAS SVSS for the analysis of low viscous liquids and the PAMAS SBSS for high viscous samples. With these specially equipped particle analysing systems, it can be easily verified if the pharmacopoeia are being respected. The PAMAS USP pharmaceutical procedural software programme provides standardised measuring reports in compliance with the pharmacopoeia USP, EP,



The PAMAS SVSS particle counting system measures infusion solutions, parenterals, intravenous or ophthalmic liquids and further pharmaceutical suspensions in compliance with the US pharmacopoeia. The measuring results are reported with the help of the pharmaceutical procedural software PAMAS USP. With the aid of a Small Volume Kit (accessory for small volume samples), the instrument can now be used to analyse Therapeutic Protein Injections as per USP 787. (Picture: PAMAS)

BP, JP and IPC. So the user can see at one glance whether the analysed sample meets the requirements of the selected standard. The PAMAS USP software can also be used to validate particle counters.

The laboratory instruments PAMAS SVSS and PAMAS SBSS are now compatible to the pharmacopoeia USP 787 (Subvisible Particulate Matter in Therapeutic Protein Injections). Up to now, it had only been possible to fulfill the pharmaceutical standards 788 (Particulate Matter in Injections) and 789 (Particulate Matter in Ophthalmic Solutions). Since PAMAS has developed accessories for small sample volumes, the instruments can also fulfil the additional pharmacopoeia USP 787. Both the PAMAS SVSS for low viscous fluids and the PAMAS SBSS for high viscous fluids can be adapted to small sample volumes. The software programme PAMAS USP monitors whether the requirements of the USP 787 standard are fulfilled.

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ZEISS C Epiplan-APOCHROMAT objectives

Compact system for surface analysis

New widefield confocal microscope ZEISS Smartproof 5 for industrial applications



ZEISS Smartproof 5 for industrial applications

The new ZEISS Smartproof 5 widefield confocal microscope is designed for a wide range of industrial applications in quality assurance and quality control departments, production environments and R&D labs. The microscope system provides 3D reconstructions and roughness measurements for a wide range of work piece surfaces. Users benefit from an integrated design, repeatable results and high throughput.

The integrated and robust design of ZEISS Smartproof 5 offers the option of installing and running it in different working environments without additional anti-vibration equipment. The optics, electronics and camera are all embedded in the microscope with the number of cables minimized to eliminate clutter.

The ZEISS Smartproof 5 software provides the user with easy-to-operate workflow routines. Teachable inspection jobs and the clearly arranged graphical user interface (GUI) guide the user through recurring tasks and ensure user-independent data acquisition as a basis for precise and traceable results. In addition to geometrical measurements, roughness analyses in 2D (profile) and 3D (area) can be carried out – both based on ISO standards. The workflows can be saved, ready to perform the same microscopic 3D analysis in future.

Thanks to the optical working principle, ZEISS Smartproof 5 is especially suited to fast production and process monitoring. Its patented technology minimizes the time to result – while the system offers both high resolution and high speed. Dedicated ZEISS optics and proven components enable the user to work effectively across a broad range of applications.

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